



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0695; FRL-9934-05]

Diethofencarb; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of diethofencarb in or on banana. Sumitomo Chemical Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0695 is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0695 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0695, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8232) by Sumitomo Chemical Company, LTD., 27-1 Shinkawa 2 Chrome, Chuo-Ku, Tokyo 104-8260, Japan. The petition requested that 40 CFR part 180 be amended by establishing a tolerance without a U.S. registration for residues of the fungicide diethofencarb in or on banana at 0.09 parts per million (ppm). That document referenced a summary of the petition prepared by Sumitomo Chemical Company, LTD, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no FFDCA-related comments received in response to the notice of filing.

Based on available data, EPA is establishing a tolerance at a level that is slightly different from what was requested. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diethofencarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with diethofencarb follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicology database is complete for diethofencarb. In repeated dose animal studies, the liver was a target organ in the rat, mouse, and dog. Increased liver pigmentation observed histologically in the dog, and foci of necrosis and hepatocellular hyperplasia in the mouse, were considered adverse and evidence of toxicity. Other target organs identified were the kidney (proteinaceous cast and regenerative epithelium), urinary bladder (submucosal lymphoid hyperplasia) and thyroid (follicular cell adenomas and carcinomas) in the rat, and the nervous system (changes in functional observational battery parameters, decreased motor activity, and decreased pupillary reflex) in the rat. The neurotoxicity in the rat, however, occurred only at high dose levels, at or above the limit dose, and were minimal in severity and there was no other evidence of neurotoxicity in the data base; therefore, there is no concern for neurotoxicity. There was no evidence of immunotoxicity in the data base, including the immunotoxicity study. Decreased body weight and food consumption and increased salivation were observed in the dog. In the pre-natal developmental studies in rats and rabbits, increased abortions were observed in the rabbit only at dose levels near the limit dose; in the multi-generation reproduction study in rats, decreased body weight was seen in F2 pups during lactation in the absence of parental toxicity, raising a concern for increased susceptibility in offspring. However, appropriate endpoints and points of departure were used to address the susceptibility issue and there are no residual pre- and/or post-natal uncertainties for offspring. The Agency has classified diethofencarb as “suggestive evidence of carcinogenicity” based on the presence of thyroid tumors in male and female rats. There was no evidence of carcinogenicity in male or female mice at dose levels that were considered adequate to assess carcinogenicity. Additionally, there is no concern for mutagenicity. Quantification of human cancer risk is not required. The chronic reference dose (RfD) will adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to diethofencarb.

Specific information on the studies received and the nature of the adverse effects caused by diethofencarb as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, “Human Health Risk Assessment for the Proposed Tolerance of Diethofencarb in/on Banana” at pp. 15-18 in docket ID number EPA-HQ-OPP-2014-0695.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to

determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or RfD - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for diethofencarb used for human risk assessment is shown in Table 1 of this unit.

Table. 1--Summary of Toxicological Doses and Endpoints for Diethofencarb for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	A toxicity endpoint was not identified. Toxicological effects attributable to a single exposure (dose) were not observed in oral toxicity studies		
Chronic dietary (All populations)	NOAEL = 50 mg/kg/day UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.50 mg/kg/day cPAD = 0.50 mg/kg/day	Chronic Toxicity, Dog LOAEL = 250 mg/kg/day based on decreased body weights and emesis
Cancer (Oral, dermal, inhalation)	Classification: "suggestive evidence of carcinogenicity to humans" based on the rat thyroid follicular cell tumors; quantification is not required		

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. RfD = Reference Dose. cPAD = chronic Population Adjusted Dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to diethofencarb, EPA assessed dietary exposures from diethofencarb in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for diethofencarb; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The assessment assumes residues of diethofencarb are present at tolerance levels and that 100% of bananas are treated with diethofencarb.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that diethofencarb was assigned the classification "suggestive evidence of carcinogenicity to humans" based on the rat thyroid tumors, but quantification is not required.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for diethofencarb. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* An assessment of residues in drinking water is not required for this assessment because diethofencarb is not registered for use in the United States, and thus, there is no exposure to diethofencarb in drinking water in the United States.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Diethofencarb is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found diethofencarb to share a common mechanism of toxicity with any other substances, and diethofencarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that diethofencarb does not have a common mechanism of toxicity with other substances. For

information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the rat developmental study, there were no indications of toxicity in the dams or fetuses up to the limit dose. An acceptable (non-guideline) rabbit developmental toxicity study showed late-term abortions (considered evidence of both maternal and fetal toxicity) at dose levels near the limit dose (800 milligram/kilogram/day (mg/kg/day) and above). In the rat reproduction study, offspring effects (decreased pup body weight in F₂ males and females) were noted below the parental NOAEL, indicating increased quantitative susceptibility in offspring. However, clear NOAELs and LOAELs are available for all parental and offspring effects and endpoints and PODs are based on the effects in the offspring.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for diethofencarb is complete.
- ii. There are no concerns for neurotoxicity and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.
- iii. There is evidence that diethofencarb results in reproductive susceptibility as shown in the multi-generation reproduction study, but the effect is well characterized; therefore, there is no need to retain the 10X FQPA safety factor to account for effects on infants and children.
- iv. There are no residual uncertainties identified in the exposure databases. The Agency used tolerance-level residues and 100 PCT. No drinking water and residential exposures are expected as there are no U.S. registrations containing diethofencarb.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For

linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, diethofencarb is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to diethofencarb from food will utilize $\leq 100\%$ of the cPAD for the general U.S. population and all population sub-groups. The most highly exposed population subgroup was children 1-2 years old with an estimated risk of $\leq 1\%$ cPAD. There are no residential uses for diethofencarb.

3. *Short-term and intermediate-term risks.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level); intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses for diethofencarb registered in the United States, no assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating risk for diethofencarb.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA has determined that diethofencarb is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to diethofencarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography method with tandem mass-spectrometry detection (HPLC/MS/MS), PTRL West Method No. 2348W) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for diethofencarb.

C. Revisions to Petitioned-For Tolerances

The requested tolerance levels differ from those being established by EPA. The petitioner used the Organization for Economic Co-operation and Development Maximum Residue Limit (OECD MRL) methodologies and entered 12 trials. EPA determined that 2 sets of trials (out of 12 total) were not independent. As a result, EPA entered 10 values only into the calculator, and is establishing a tolerance level slightly higher than what was proposed.

V. Conclusion

Therefore, a tolerance is established for residues of diethofencarb, in or on banana at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 21, 2015.

Jack E. Housenger,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.688 to subpart C to read as follows:

§ 180.688 Diethofencarb; tolerance for residue.

(a) *General.* (1) Tolerances are established for residues of the fungicide diethofencarb, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only diethofencarb (1-methylethyl *N*-(3,4-diethoxyphenyl)carbamate).

Commodity	Parts per million
Banana*	0.10

* There is no U.S. registration for use on this commodity as of [insert date of publication].

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues* [Reserved]

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